

**REMARKS**

**Pending claims**

Claims 63-81 are currently pending in the application.

**Restriction Requirement**

In the Restriction Requirement, the Examiner requested Applicants to elect one of the following inventions:

Groups I-IX. Claims 1-2, drawn to isolated protein kinase homologs PKH1-9 classified in class 435, subclass 194.

Groups X-XXVI Claims 3-7, 9, 11-12, 54-62, drawn to isolated polynucleotides encoding said enzymes vectors and hose cell comprising said polynucleotides, methods of expressing said polynucleotides, classified in class 435, subclass 194.

Groups XXVII-XXXV. Claim 8, drawn to transgenic organisms comprising said polynucleotides classified in class 435, subclass 194.

Groups XXXVI-XXXIV. Claims 13-15 drawn to a method of detecting a target polynucleotide wherein the target polynucleotide is chosen from ONE of the following: SEQ ID NO: 10-18, classified in class 435, subclass 6.

Groups VL-LIV Claims 63-65, 67-68, 70, 73-74, 76-79 drawn to a antibody to ONE of the following: SEQ ID NO: 1-9, classified in class 530, subclass 387.1.

Groups LV-LXIII Claims 66, 69, 71, 80 drawn to a method of detecting a condition or disease with an antibody to ONE of the following: SEQ ID NO: 1-9, classified in class 435, subclass 387.1.

Group LXIV-LXXII Claims 72, 75 81 drawn to a method of making an antibody to ONE of the following: SEQ ID NO: 1-9, classified in class 435, subclass 69.6

In response to the Restriction Requirement, Applicants elect the “antibody” subject matter of claims 63-65, 67, 68, 70, 73, 74 and 76-79, with traverse. Further Applicants elect, with traverse, to prosecute the invention relating to SEQ ID NO:5. Applicants reserve the right to prosecute the subject matter of non-elected claims in subsequent divisional applications. Applicants traverse this Restriction Requirement on several grounds.

Applicants also submit that claims 66, 69, 71 and 80, drawn to methods of use of the antibodies, and claims 72, 75 and 81, drawn to methods of making the antibodies, should be examined together with the elected claims. These method claims recite a product (e.g. antibodies) which is of the same scope as the claimed antibodies being searched by the Examiner. Therefore, it would not be an undue burden on the Examiner to examine these method claims since the searches for the claimed antibodies and these method claims would substantially overlap. Additionally, these method claims are entitled to rejoinder upon allowance of a product claim per the Commissioner’s Notice in the Official Gazette of March 26, 1996, entitled “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)” which sets forth the rules, upon allowance of a product claim, for rejoinder of process claims covering the same scope of products.

In regard to the election of species of a particular sequence, Applicants traverse on the grounds that the Examiner examined all nine polypeptide sequences (i.e., SEQ ID NO:1-9) in not one, but two ancestor applications: U.S. Application Serial No.’s 09/173,581 and 09/420,915, now U.S. Patent No.’s 6,013,455 and 6,264,947, respectively. Thus, restriction to a single sequence at this time would be unfair as it would contradict the Examiner’s positions in the two previous applications that such sequences not be so restricted.

Further according to MPEP §803, a restriction requirement is proper only if (A) the inventions are independent or distinct as claimed, and (B) there would be a serious burden on the Examiner if restriction was not required. Here the restriction requirement is clearly improper given the fact that all nine sequences were examined, and thus searched, in not one, but two

previous applications. Thus, the examination of those sequences in the instant application would certainly not present a serious burden on the Examiner.

Applicants also traverse this restriction requirement insofar as it is, in effect, a requirement for election of species as between elements in Markush groups (those elements being, respectively, SEQ ID NO:1-9 with respect to antibodies and the polypeptides to which they specifically bind). The Examiner's attention is directed to the Patent Office's own requirements for Markush practice, set forth in the 8<sup>th</sup> edition of the M.P.E.P. (August 2001) at § 803.02 regarding restriction requirements in Markush-type claims: PRACTICE RE MARKUSH-TYPE CLAIMS

If the members of the Markush group are **sufficiently few in number or so closely related** that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction.

Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), **it is improper for the Office to refuse to examine that which applicants regard as their invention**, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, **unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.**

This subsection deals with Markush-type generic claims which include a plurality of alternatively usable substances or members. In most cases, a recitation by enumeration is used because there is no appropriate or true generic language. A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing claims of that nature, **the examiner may require a provisional election of a single species** prior to examination on the merits. The provisional election will be given effect in the event that the Markush-type claim should be found not allowable. Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable over the prior art, examination will be limited to the Markush-type

claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

As an example, in the case of an application with a Markush-type claim drawn to the compound C-R, wherein R is a radical selected from the group consisting of A, B, C, D, and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD, or CE. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the nonelected species would be held withdrawn from further consideration. As in the prevailing practice, a second action on the rejected claims would be made final.

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a *non-elected species*, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry. [emphasis added]

As can be seen from the above, the present Restriction Requirement does not meet the Patent Office's own requirements. First and foremost, if the number of "members of the Markush group are **sufficiently few in number or so closely related** that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. **In such a case, the examiner will not follow the procedure described below and will not require restriction.**" Withdrawal of the restriction requirement as between the nine specific sequences each in the claims is required on that basis alone. Corroboration for the fact that the nine sequences are indeed sufficiently few in number or so closely related, all being protein kinases, that a search and examination of the entire claim can be made without serious burden is found in the fact that the Examiner has already examined all nine sequences in two ancestor applications.

Second, it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility.” Clearly, the antibodies of the present invention share a common utility, for example, detection of a disease associated with the expression the polypeptides of SEQ ID NO:1-9. They also share a substantial structural feature in that the polypeptides to which they specifically bind, SEQ ID NO:1-9, are protein kinases.

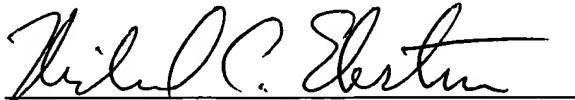
Third, even if the claims could be considered to be “Markush-type generic claims which include a plurality of alternatively usable substances or members,” it is further noted that the M.P.E.P states that “A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing claims of that nature, **“the examiner may require a provisional election of a single species** prior to examination on the merits” but if no prior art is found, examination must continue on the other claimed species. This clearly applies in the present case.

Therefore, it is respectfully submitted that, upon searching and examining the antibodies which specifically bind to the polypeptides related to SEQ ID NO:5, and finding no prior art over which they can be rejected, the Examiner must extend the search of the Markush-type claim to include the non-elected species.


Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 09-0108.

Respectfully submitted,  
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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE CLAIMS:**

Claims 1-9, 11-15 and 54-62 have been canceled.